DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 17, 2014

Unicon Optical Co., Ltd.
% Mr. Michael Lee
President
No. 45, Mingsheng Rd., Danshui District
New Taipei, 251 TW

Re: K141917
Trade/Device Name: Unicon (Etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: July 8, 2014
Received: July 15, 2014

Dear Mr. Lee,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141917

Device Name
Unicon (etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear

Indications for Use *(Describe)*

The UNICON (etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear is indicated for the correction of ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eye who may have 1.00 D or less astigmatism. The UNICON (etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear are single disposable wear and are to be discarded after each removal. UNICON (etafilcon A) Soft (hydrophilic) Contact Lens with UV Blocker for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 7th July, 2014

5.3 Submitter: UNICON Optical Co., LTD.

Address:	No 16, Gongye E. 9th Rd., Hsinchu Science Park, Baoshan Township, Hsinchu County 30075, Taiwan
Phone:	+886-3-5775586
Fax:	+886-3-5777868
Contact:	Robert

5.4 Identification of the Device:

Proprietary/Trade name:	UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear
Common Name:	Soft (hydrophilic) contact lenses for daily wear
Classification Name:	LENS, CONTACT, (DISPOSABLE)
Device Classification:	II
Regulation Number:	886.5925
Panel:	Ophthalmic
Product Code:	MVN；LPL

5.5 Identification of the Predicate Device:

Predicate Device Name:	VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear
Manufacturer:	VISTAKON
Product Code:	MVN；LPL
510(k) Number:	K051900

5.6 Intended Use and Indications for Use of the subject device.

The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear is indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less astigmatism. The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear are indicated for single-use disposable wear and are to be discarded after each removal. The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.

5.7 Device Description

UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear is available as aspherical lenses manufactured by case-molding method. The model illuminated with high water content (58 %). The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with Trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo-polymerization. The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear with visible tint is light tinted blue using Blue 15:3 to make the lens more visible for handling. The lenses also contain a UV absorber {2-[3-(2H-Benzotriazol-2-yl)-4-hydroxyphenyl] ethyl methacrylate} which is included during the manufacturing process as a monomer to block UV radiation. The average transmittance characteristics are less than 5% in the UVB range of 280 to 315 nm and less than 30% in the UVA range of 316 to 380nm.

With more specific explanation, the “UNICON (Etafilcon A) Soft (Hydrophilic)

Contact Lens with UV Blocker for Daily Wear" is 58% water and 42% HEMA/MAA cast-molding aspherical soft contact lens. It is blister packaged and produced from +4.00D to -6.00D in 0.25D per step, from +4.50D to +6.00D in 0.50D per step, and from -6.50D to -13.00D in 0.50D per step.

5.8 Non-clinical Testing

A series of non-clinical studies were completed on this product. The tests and studies were performed in UNICON QC lab and subcontracted test services which were according to the FDA guidance (Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, February 27, 1997) and related recognized consensus standards. All the test results were met the requirements of products specification.

The following tests were conducted on "UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear":

- Sterilization Test
- Shelf Life Test
- Biocompatibility
  - Cytotoxicity
  - Irritation
  - Acute Systemic toxicity
- Water Content
- Mechanical Properties of Materials
- Refractive Index
- Oxygen Permeability
- Transmittance
- Extractables Test

- Specific Gravity

The Sterilization Method used on "UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear" is moist heat sterilization and the study for sterilization is based on the EN/ISO 17665：2006 Sterilization of health care product—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. The overkill method is used as validation method for sterilization validation and the results demonstrates achievement of the required sterility assurance limit (SAL) of 10^{-6}.

5.9 Clinical Testing

The safety and effectiveness of etafilcon A lenses have been established through previous clinical performance testing. And the pre-clinical testing results are sufficient in establishing substantial equivalence.

5.10 EMC and Electrical safety

The devices do not require EMC/Electrical Safety evaluation.

5.11 Substantial Equivalence Determination

The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the cleared VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear which is the subject of K051900. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

	Proposed Device	Predicate Device
Device name	UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear	VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear
Regulatory Number	886.5925	886.5925
Classification	II	II
Intended Use	The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear is indicated for daily wear for the correction of ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.00D or less astigmatism. The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear are indicated for single-use disposable wear and are to be discarded after each removal. The UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear helps protect against transmission of harmful UV radiation to the cornea and into the eye.	The VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens (spherical), Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with not diseased eyes who may have 1.00D or less of astigmatism. VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear help protect against transmission of harmful UV radiation to the cornea and into the eye. The VISTAKON (Etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Visibility Tinted with UV Blocker for Daily Disposable Wear is to be prescribed for Daily Disposable Wear and is to be discarded after each removal.
Prescription Use	Yes	Yes
Single Use	Yes	Yes

Material	Etafilcon A	Etafilcon A
Base Curve	7.85mm to 10.0mm	7.85mm to 10.0mm
Diameter	12.0mm to 15.0mm	12.0mm to 15.0mm
Water Content	58%	58%
UV transmittance @280~315 nm @316~380 nm	Avg < 5% Avg < 30%	Avg < 5% Avg < 30%
UV absorbing	Benzotriazol	Benzotriazole
Refractive Index	1.399	1.40
Manufacturing Method	Cast Molded	Cast Molded
Sterilization method	Traditional moist heat	Traditional moist heat
Primary packaging	PP container with aluminum foil sealing	PP container with aluminum foil sealing
Power	+6.00D to -13.00D	+20.00D to -20.00D
Specific Gravity	1.14	0.98-1.12
Tensile Strength	1.66 Mpa	2.00 Mpa
Break Elongation	393%	189%
Secant Modulus	0.43 Mpa	1.06 Mpa
Oxygen permeability (edged corrected) @ 35℃	30.8×10^{-11} (cm^2/sec) (mlO_2/ml-mmHg)	28×10^{-11} (cm^2/sec) (mlO_2/ml-mmHg)
Visible Light Transmittance	Minimum 90%	Minimum 85%
Color & Tint	Blue 15:3	Reactive Blue Dye #4
FDA 21 CFR (Color additive)	74.3045 [Phthalocyaninato(2-)] copper	73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers

5.12 Similarity and differences

The difference between the proposed device and predicate device is color additive. The color additive used on proposed device is Blue 15:3 ([Phthalocyaninato (2-)]copper) which has already been approved by US FDA. According to FDA 21 CFR §74.3045, this color additive may be safely used for coloring contact lenses. Therefore, the difference of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in intended use, main materials, design, safety and performance claims.

5.13 Conclusion

After analyzing bench tests and clinical test, it can be concluded that UNICON (Etafilcon A) Soft (Hydrophilic) Contact Lens with UV Blocker for Daily Wear is substantially equivalent to the predicate device.